

Politics

Suspend AstraZeneca use for people under 55, vaccine committee recommends

The updated guidelines come following reports of rare blood clots

[David Cochrane](#), [John Paul Tasker](#) · CBC News ·

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Prince Edward Island announced Monday that it is suspending its AstraZeneca-Oxford vaccine program, which was geared to 18-29-year-olds, pending 'further information' from Health Canada. (Matthias Schrader/The Associated Press)

Canada's National Advisory Committee on Immunization (NACI) is recommending provinces pause the use of the AstraZeneca-Oxford COVID-19 vaccine on those under the age of 55 because of safety concerns — guidance most provinces said today that they would follow.

The change comes following reports out of Europe of very rare instances of blood clots in some immunized patients — notably among younger women.

But 300,000 of these shots have been administered in Canada already, with no reports of blood clots here, officials said. The blood clotting problem also has not been reported in people who have received mRNA vaccines like the Pfizer and Moderna products.

Speaking to reporters Monday, Dr. Shelley Deeks, the vice-chair of NACI, said that with "substantial uncertainty" around cases of vaccine-induced [thrombocytopenia](#) (VIPIT) in people with low platelets, the committee is recommending the suspension of shots in all people under 55 as a "precautionary measure."

Based on early research out of Europe, VIPIT seems to be rare, occurring in anywhere from 1 in every 125,000 to 1 in 1 million people.

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The European Union's drug watchdog, the European Medicines Agency, has said it could not definitively rule out a link between the vaccine and rare types of blood clots associated with [thrombocytopenia](#).

Specifically, it pointed to 18 cases of an extremely rare type of blood clot called cerebral venous sinus thrombosis (CVST), a condition that is much more common in women than men. Most of the cases occurred within 14 days of receiving the AstraZeneca shot, and the majority were in women under the age of 55.

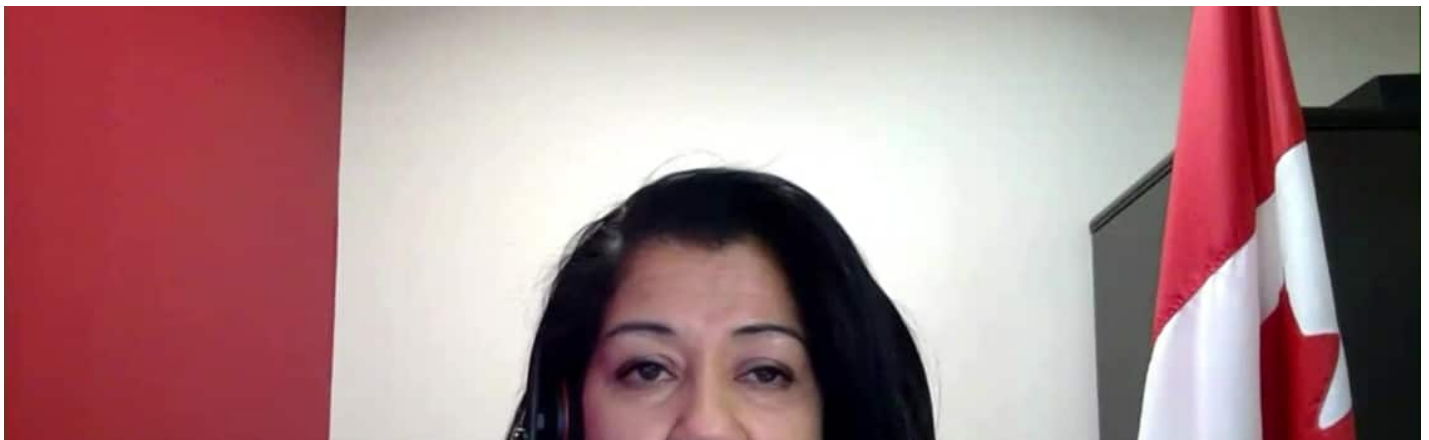
Dr. Howard Njoo, Canada's deputy chief public health officer, said people who develop stroke-like medical symptoms after receiving the AstraZeneca vaccine — shortness of breath, chest pain, leg swelling, abdominal pain, sudden onset of headaches or blurred vision — should immediately seek medical attention. There is no risk for people who have not developed such symptoms 20 days post-vaccination.

Asked why the shot is still recommended for people over the age of 55 given the many unknowns, Dr. Caroline Quach-Thanh, the chair of NACI, said the early data indicate that the rare blood clots are most common in younger people.

She said older Canadians should take whatever vaccine they can get because contracting COVID-19 poses a much greater health risk to them than the outside chance of developing this sort of blood clot.

"If you look at this overall, it's a vaccine that prevents complications and deaths. We're trying to contrast the risks and benefits," she said.

WATCH: Vaccine committee recommends a pause on use of AstraZeneca vaccine among those under 55



Vaccine committee recommends a pause on use of AstraZeneca COVID-19 vaccine on those under the age of 55

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Dr. Supriya Sharma, Health Canada's chief medical adviser, discusses NACI's recommendation to pause the use of AstraZeneca's COVID-19 vaccine on those under the age of 55.

Quach-Thanh conceded the barrage of bad headlines about AstraZeneca could increase vaccine hesitancy but said that with the pandemic running "rampant," seniors should get a shot that greatly reduces their risk of COVID-19-related death and hospitalization.

"This vaccine has had all the ups and downs — its looks like a roller coaster," she said, citing the changing guidelines on AstraZeneca.

Asked if he still has confidence in the safety of this product, Marc Berthiaume, the director of the bureau of medical science at Health Canada, said reports of rare, adverse health events are always possible when millions of people are treated with a vaccine.

"This vaccine remains relevant," he said.

"This is something that is very rare and we need to continue to monitor it," said Dr. Supriya Sharma, Health Canada's chief medical adviser, adding this is a sign that Canada has a robust monitoring system.

"It's reasonable to pause for a period of time while this continues to be evaluated," she said. "I fully understand this can be confusing."

“... the benefits of using our vaccine to protect people from this deadly virus significantly outweigh the risks across all adult age groups.”

- AstraZeneca Canada

The policy shift comes as Canada is expected to receive 1.5 million doses of this product from the U.S. on Tuesday. The product has not yet been approved for use in the American marketplace.

The AstraZeneca shot has not been widely used in people under the age of 55 in this country.

Some jurisdictions, such as B.C. and P.E.I., have been using some of their supply to immunize young people who work in public-facing sectors like grocery and convenience stores. In New

Brunswick, the shot was made available to first responders and some teachers last week.

Meanwhile, Health Canada — which approved the vaccine for use in Canada in February — said its regulators would be adding "additional terms and conditions on the authorizations" for AstraZeneca and a biologically identical version of the drug manufactured by the Serum Institute of India, which has been branded Covishield.

The manufacturers will be required to conduct a "detailed assessment of the benefits and risks of the vaccine by age and sex in the Canadian context," information that could lead to "additional regulatory actions."

"This information will support the ongoing evaluation of these rare blood clotting events, and allow Health Canada to determine if there are specific groups of people who may be at higher risk," the department said in a press release.

Benefits outweigh risks: AstraZeneca

AstraZeneca issued a statement this evening saying that it respects the decision by NACI and noting that Health Canada's guidance on the vaccine has not changed since last week.

"Regulatory authorities in the U.K., European Union, the World Health Organization and Health Canada have concluded that the benefits of using our vaccine to protect people from this deadly virus significantly outweigh the risks across all adult age groups," said AstraZeneca spokesperson Carlo Mastrangelo in the statement.

The statement went on to say that tens of millions of people around the world have now taken the AstraZeneca vaccine and "real-world evidence demonstrates its effectiveness."

"Patient safety remains the company's highest priority. We continue to work closely with Health Canada to share and submit safety data as it becomes available to ensure the appropriate use of our vaccine," Mastrangelo said.

'We just won't use it, simple as that': Ford

Speaking to reporters in Niagara Falls, Ont., Ontario Premier Doug Ford said today that the province would follow NACI's guidance and reserve the current supply of AstraZeneca for those

in the older cohort.

"I won't hesitate to cancel that in half a heartbeat. If it's going to put anyone in harm, we just won't use it, simple as that," he said, adding he didn't want to "roll the dice" by using AstraZeneca on a group that may have an outsized chance of developing complications.

"The guidance from the federal government is that it is safe for people over 55," Ford said. "I'm talking about younger people taking it, 35 years of age and in that range, that's where the problem is."

Dr. Joss Reimer, the medical lead on Manitoba's vaccine implementation task force, said that the province also would pause its deployment of the vaccine among people under 55 because of a "very rare subtype, one specific type of blood clot."

She said that while there have been no complications reported in Canada, "out of an abundance of caution" Manitoba will restrict the shot to people 55 to 64, for now.

"This is a pause while we wait for more information to better understand what's happened in Europe. This is an important and evidence-based change," she said.

Watch: Vaccine committee chair addresses AstraZeneca COVID-19 vaccine hesitancy:



Vaccine committee chair addresses AstraZeneca COVID-19 vaccine hesitancy

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Dr. Caroline Quach-Thanh, chair of the National Advisory Committee on Immunization, responds to questions about Canadians being hesitant to receive the AstraZeneca COVID-19 vaccine.

Reimer said it's "probably" fine to use the vaccine on all groups — but she's not comfortable with just "probably" and wants to wait to see more data from Europe.

This is just the latest issue the company has faced over the last three months.

Earlier this year, a number of European countries halted vaccinations in response to questions about the AstraZeneca product's efficacy in people over the age of 65, only to restart them after new evidence emerged.

After Health Canada approved the shot for all adults, NACI recommended the product be used only on people under the age of 65, citing a dearth of clinical trial data on the vaccine's effectiveness in older people.

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- **SECOND OPINION** [Canada monitoring guidance on AstraZeneca-Oxford vaccine amid potential link to blood clots](#)

NACI changed course earlier this month after reviewing three "real-world studies," saying the two-dose viral vector vaccine can and should be used on seniors.

Last week, the U.S. Data and Safety Monitoring Board (DSMB), which keeps an eye on clinical trials, found "outdated information" may have been reported by the company when it released data on U.S. trials.

Dr. Anthony Fauci, U.S. President Joe Biden's chief medical adviser and the head of the NIAID, said the monitoring board was surprised by the the better-than-expected efficacy results published by AstraZeneca.

WATCH / 'It doesn't take much for a vaccine to be voted off the island,' says top vaccine researcher





'It doesn't take much for a vaccine to be voted off the island,' says top vaccine researcher

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Dr. Peter Hotez, dean of the National School of Tropical Medicine at Baylor College of Medicine, says the vaccine ecosystem is fragile and the messaging around the AstraZeneca vaccine could cause the public to lose confidence in it even if it's safe and effective.

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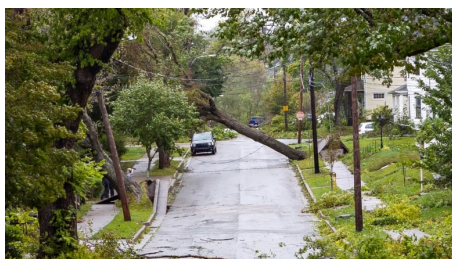
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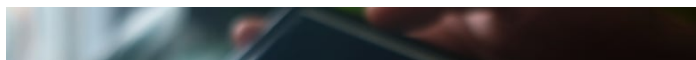
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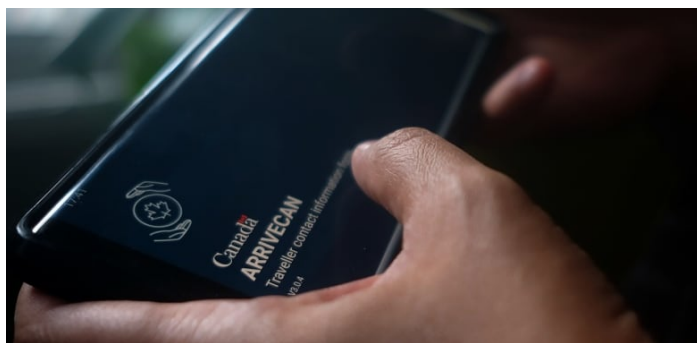
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